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EXAMINER

HARVEY, JULIANNA NANCY

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/731,964	Applicant(s) BENZEL ET AL.	
	Examiner Julianna N. Harvey	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 7 recites the limitation “one of said first retaining member and said first mounting member includes a stop” and claim 25 recites the limitation “one of said first retaining member and said first mounting member includes a first stop...one of said second retaining member and said second mounting member including a second stop.” The only reference to a “stop” in the specification is located on page 17, lines 4-14 where it is recited that “[t]he central ribs 28 and 68 on the upper and lower retaining members 21 and 61 act as stops.” There is no mention of either of the mounting members containing a stop and thus claims 7 and 25 are not in compliance with the written description requirement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-13, 16-21, 23-29, and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrington (US 5,893,889).

- Claim 1: Harrington discloses an apparatus for replacing a damaged spinal disc in a spinal column, said apparatus comprising: an artificial disc (see prosthetic disc “18” in figure 2), said artificial disc including a resilient core (see shock absorbing member “68” in figure 2) having a first surface (see upper surface of “68” in figure 2) and a second surface (see lower surface of “68” in figure 2), a first retaining member (see upper member “32” in figure 2) connected to said first surface of said resilient core, and a second retaining member (see lower member “34” in figure 2) connected to said second surface of said resilient core, said first retaining member having an outer surface (see upper surface “36” in figure 2) engageable with a first vertebra of the spinal column and an inner surface (see lower surface “58” in figure 2) facing said first surface of said resilient core, said second retaining member having an outer surface (see lower surface “40” in figure 2) engageable with a second vertebra of the spinal column and an inner surface (see upper surface “44” in figure 2) facing said second surface of said resilient core; and a first mounting member (see screws “64” and “66” in figure 2) connectable

with the first vertebra and said artificial disc to position said artificial disc between the first and second vertebrae, said first mounting member being engageable with said artificial disc after being connected to the first vertebra to guide movement of said artificial disc into position between the first and second vertebrae.

- Claim 2: An apparatus as defined in claim 1 wherein one of said first retaining member (see upper member “32” in figure 2) and said first mounting member (see screws “64” and “66” in figure 2) includes a guide (see angled openings of holes “60” in figure 2) engageable with another of said first retaining member and said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae.
- Claim 3: An apparatus as defined in claim 2 wherein said first retaining member (see upper member “32” in figure 2) includes said guide (see angled openings of holes “60” in figure 2) engageable with said first mounting member (see screws “64” and “66” in figure 2).
- Claim 5: An apparatus as defined in claim 1 wherein one of said first retaining member (see upper member “32” in figure 2) and said first mounting member (see screws “64” and “66” in figure 2) includes first and second guides (see angled openings of holes “60” in figure 2) engageable with another of said first retaining member and said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae.
- Claim 6: An apparatus as defined in claim 5 wherein said first retaining member (see upper member “32” in figure 2) includes said first and second guides (see angled

openings of holes “60” in figure 2) engageable with said first mounting member (see screws “64” and “66” in figure 2), said first and second guides extending generally parallel to each other.

- Claim 7: An apparatus as defined in claim 1 wherein one of said first retaining member (see upper member “32” in figure 2) and said first mounting member (see screws “64” and “66” in figure 2) includes a stop (see tapered portions of holes “60” in figure 2) engageable with another of said first retaining member and said first mounting member to prevent relative movement between said first retaining member and said first mounting member in a first direction.
- Claim 8: An apparatus as defined in claim 7 wherein said first retaining member (see upper member “32” in figure 2) includes said stop (see tapered portions of holes “60” in figure 2) engageable with said first mounting member (see screws “64” and “66” in figure 2) to prevent relative movement between said first retaining member and said first mounting member in the first direction, said stop guiding movement of said first retaining member relative to said first mounting member in a second direction extending transverse to the first direction.
- Claim 9: An apparatus as defined in claim 1 wherein one of said first retaining member (see upper member “32” in figure 2) and said first mounting member (see screws “64” and “66” in figure 2) includes a guide (see angled openings of holes “60” in figure 2) engageable with another of said first retaining member and said first mounting member to guide movement of said first mounting member into an opening (see holes “60” in figure 2) in said first retaining member.

- Claim 10: An apparatus as defined in claim 1 wherein said first retaining member (see upper member “32” in figure 2) has an opening (see holes “60” in figure 2) extending through said inner (see lower surface “58” in figure 2) and outer (see upper surface “36” in figure 2) surfaces of said first retaining member, said first mounting member (see screws “64” and “66” in figure 2) extending into said opening.
- Claim 11: An apparatus as defined in claim 10 wherein said opening (see holes “60” in figure 2) extends axially through said inner (see lower surface “58” in figure 2) and outer (see upper surface “36” in figure 2) surfaces of said first retaining member (see upper member “32” in figure 2).
- Claim 12: An apparatus as defined in claim 1 wherein said first mounting member (see screws “64” and “66” in figure 2) is engageable with a surgical tool for connecting said first mounting member to the first vertebra.
- Claim 13: An apparatus as defined in claim 12 wherein said first mounting member (see screws “64” and “66” in figure 2) includes a recess (see slit in heads of screws “64” and “66” in figure 2) into which a portion of said surgical tool extends for connecting said first mounting member to the surgical tool.
- Claim 16: An apparatus as defined in claim 1 wherein said first mounting member (see screws “64” and “66” in figure 2) is prevented from moving relative to said artificial disc (see prosthetic disc “18” in figure 2) when said first mounting member is connected to said artificial disc.
- Claim 17: An apparatus as defined in claim 16 wherein said first mounting member (see screws “64” and “66” in figure 2) is connected to said artificial disc (see prosthetic

disc “18” in figure 2) with an interference fit (see heads of screws “64” and “66” and tapered portions of holes “60” in figure 2).

- Claim 18: An apparatus as defined in claim 17 wherein said first mounting member (see screws “64” and “66” in figure 2) has a frustoconical surface (see heads of screws “64” and “66” in figure 2) engageable with a frustoconical surface (see tapered portions of holes “60” in figure 2) on said artificial disc (see prosthetic disc “18” in figure 2).
- Claim 19: An apparatus as defined in claim 1 further including a second mounting member (see screws “47” and “48” in figure 2) connectable with the second vertebra and said artificial disc (see prosthetic disc “18” in figure 2) to position said artificial disc between the first and second vertebrae, said second mounting member being engageable with said artificial disc to guide movement of said second retaining member (see lower member “34” in figure 2) into position between the first and second vertebrae.
- Claim 20: An apparatus as defined in claim 19 wherein one of said first retaining member (see upper member “32” in figure 2) and said first mounting member (see screws “64” and “66” in figure 2) includes a first guide (see angled openings of holes “60” in figure 2) engageable with another of said first retaining member and said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae, one of said second retaining member (see lower member “34” in figure 2) and said second mounting member (see screws “47” and “48” in figure 2) including a second guide (see angled openings of unlabeled holes in “34” in figure 2) engageable with another of said second retaining member and said

second mounting member to guide movement of said second retaining member into position between the first and second vertebrae.

- Claim 21: An apparatus as defined in claim 20 wherein said first retaining member (see upper member “32” in figure 2) includes said first guide (see angled openings of holes “60” in figure 2) engageable with said first mounting member (see screws “64” and “66” in figure 2), said second retaining member (see lower member “34” in figure 2) including said second guide (see angled openings of unlabeled holes in “34” in figure 2) engageable with said second mounting member (see screws “47” and “48” in figure 2).
- Claim 23: An apparatus as defined in claim 19 wherein one of said first retaining member (see upper member “32” in figure 2) and said first mounting member (see screws “64” and “66” in figure 2) includes first and second guides (see angled openings of holes “60” in figure 2) engageable with another of said first retaining member and said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae, one of said second retaining member (see lower member “34” in figure 2) and said second mounting member (see screws “47” and “48” in figure 2) including third and fourth guides (see angled openings of unlabeled holes in “34” in figure 2) engageable with another of said second retaining member and said second mounting member to guide movement of said second retaining member into position between the first and second vertebrae.
- Claim 24: An apparatus as defined in claim 23 wherein said first retaining member (see upper member “32” in figure 2) includes said first and second guides (see angled openings of holes “60” in figure 2) engageable with said first mounting member (see

screws “64” and “66” in figure 2), said first and second guides extending generally parallel to each other, said second retaining member (see lower member “34” in figure 2) including said third and fourth guides (see angled openings of unlabeled holes in “34” in figure 2) engageable with said second mounting member (see screws “47” and “48” in figure 2), said third and fourth guides extending generally parallel to each other.

- Claim 25: An apparatus as defined in claim 19 wherein one of said first retaining member (see upper member “32” in figure 2) and said first mounting member (see screws “64” and “66” in figure 2) includes a first stop (see tapered portions of holes “60” in figure 2) engageable with another of said first retaining member and said first mounting member to prevent relative movement between said first retaining member and said first mounting member in a first direction, one of said second retaining member (see lower member “34” in figure 2) and said second mounting member (see screws “47” and “48” in figure 2) including a stop (see tapered portions of unlabeled holes in “34” in figure 2) engageable with another of said second retaining member and said second mounting member to prevent relative movement between said second retaining member and said second mounting member in the first direction.

- Claim 26: An apparatus as defined in claim 25 wherein said first retaining member (see upper member “32” in figure 2) includes said first stop (see tapered portions of holes “60” in figure 2) engageable with said first mounting member (see screws “64” and “66” in figure 2) to prevent relative movement between said first retaining member and said first mounting member in the first direction, said first stop guiding movement of said first retaining member relative to said first mounting member in a direction extending

transverse to the first direction, said second retaining member (see lower member “34” in figure 2) including said second stop (see tapered portions of unlabeled holes in “34” in figure 2) engageable with said second mounting member (see screws “47” and “48” in figure 2) to prevent relative movement between said second retaining member and said second mounting member in the first direction, said second stop guiding movement of said second retaining member relative to said second mounting member in a direction extending transverse to the first direction.

- Claim 27: An apparatus as defined in claim 19 wherein one of said first retaining member (see upper member “32” in figure 2) and said first mounting member (see screws “64” and “66” in figure 2) includes a first guide (see angled openings of holes “60” in figure 2) engageable with another of said first retaining member and said first mounting member to guide movement of said first mounting member into an opening (see holes “60” in figure 2) in said first retaining member, one of said second retaining member (see lower member “34” in figure 2) and said second mounting member (see screws “47” and “48” in figure 2) including a second guide (see angled openings of unlabeled holes in “34” in figure 2) engageable with another of said second retaining member and said second mounting member to guide movement of said second mounting member into an opening (see unlabeled holes in “34” in figure 2) in said second retaining member.

- Claim 28: An apparatus as defined in claim 19 wherein said first retaining member (see upper member “32” in figure 2) has an opening (see holes “60” in figure 2) extending through said inner (see lower surface “58” in figure 2) and outer (see upper

surface “36” in figure 2) surfaces of said first retaining member, said first mounting member (see screws “64” and “66” in figure 2) extending into said opening in said first retaining member, said second retaining member (see lower member “34” in figure 2) having an opening (see unlabeled holes in “34” in figure 2) extending through said inner (see upper surface “44” in figure 2) and outer (see lower surface “40” in figure 2) surfaces of said second retaining member, said second mounting member (see screws “47” and “48” in figure 2) extending into said opening in said second retaining member.

- Claim 29: An apparatus as defined in claim 28 wherein said opening (see holes “60” in figure 2) in said first retaining member (see upper member “32” in figure 2) extends axially through said inner (see lower surface “58” in figure 2) and outer (see upper surface “36” in figure 2) surfaces of said first retaining member, said opening (see unlabeled holes in “34” in figure 2) in said second retaining member (see lower member “34” in figure 2) extending axially through said inner (see upper surface “44” in figure 2) and outer (see lower surface “40” in figure 2) surfaces of said second retaining member.

- Claim 32: An apparatus as defined in claim 19 wherein said first (see screws “64” and “66” in figure 2) and second (see screws “47” and “48” in figure 2) mounting members are prevented from moving relative to said artificial disc (see prosthetic disc “18” in figure 2) when said first and second mounting members are connected to said artificial disc.

- Claim 33: An apparatus as defined in claim 32 wherein said first (see screws “64” and “66” in figure 2) and second (see screws “47” and “48” in figure 2) mounting members are connected to said artificial disc (see prosthetic disc “18” in figure 2) with

interference fits (see heads of screws “64” and “66” and tapered portions of holes “60” in figure 2; see heads of screws “47” and “48” and tapered portions of unlabeled holes in “34” in figure 2).

- Claim 34: An apparatus as defined in claim 33 wherein said first (see screws “64” and “66” in figure 2) and second (see screws “47” and “48” in figure 2) mounting members have frustoconical surfaces (see heads of screws “64” and “66” and heads of screws “47” and “48” in figure 2) engageable with frustoconical surfaces (see tapered portions of holes “60” and tapered portions of unlabeled holes in “34” in figure 2) on said artificial disc (see prosthetic disc “18” in figure 2).

Claims 1-4, 19-22, 35-36, and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryan et al. (US 6,156,067).

- Claim 1: Bryan et al. disclose an apparatus for replacing a damaged spinal disc in a spinal column, said apparatus comprising: an artificial disc, said artificial disc including a resilient core (see supple nuclear central portion “24” of resilient disc body “20” in figure 3) having a first surface (see upper surface of “24” in figure 3) and a second surface (see lower surface of “24” in figure 3), a first retaining member (see support “32” in figure 3) connected to said first surface of said resilient core, and a second retaining member (see support “34” in figure 3) connected to said second surface of said resilient core, said first retaining member having an outer surface (see outer surface “52” in figure 3) engageable with a first vertebra of the spinal column and an inner surface (see inner surface “62” in figure 3) facing said first surface of said resilient core, said second retaining member having an outer surface (see outer surface “54” in figure 3)

engageable with a second vertebra of the spinal column and an inner surface (see inner surface “64” in figure 3) facing said second surface of said resilient core; and a first mounting member (see screw “92” in figure 3) connectable with the first vertebra and said artificial disc to position said artificial disc between the first and second vertebrae, said first mounting member being engageable with said artificial disc after being connected to the first vertebra to guide movement of said artificial disc into position between the first and second vertebrae.

- Claim 2: An apparatus as defined in claim 1 wherein one of said first retaining member (see support “32” in figure 3) and said first mounting member (see screw “92” in figure 3) includes a guide (see screw anchor “102” in figure 3) engageable with another of said first retaining member and said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae.
- Claim 3: An apparatus as defined in claim 2 wherein said first retaining member (see support “32” in figure 3) includes said guide (see screw anchor “102” in figure 3) engageable with said first mounting member (see screw “92” in figure 3).
- Claim 4: An apparatus as defined in claim 3 wherein said guide (see screw anchor “102” in figure 3) extends from said outer surface (see outer surface “52” in figure 3) of said first retaining member (see support “32” in figure 3) and is engageable with the first vertebra.
- Claim 19: An apparatus as defined in claim 1 further including a second mounting member (see screw “94” in figure 3) connectable with the second vertebra and said

artificial disc to position said artificial disc between the first and second vertebrae, said second mounting member being engageable with said artificial disc to guide movement of said second retaining member (see support “34” in figure 3) into position between the first and second vertebrae.

- Claim 20: An apparatus as defined in claim 19 wherein one of said first retaining member (see support “32” in figure 3) and said first mounting member (see screw “92” in figure 3) includes a first guide (see screw anchor “102” in figure 3) engageable with another of said first retaining member and said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae, one of said second retaining member (see support “34” in figure 3) and said second mounting member (see screw “94” in figure 3) including a second guide (see screw anchor “104” in figure 3) engageable with another of said second retaining member and said second mounting member to guide movement of said second retaining member into position between the first and second vertebrae.
- Claim 21: An apparatus as defined in claim 20 wherein said first retaining member (see support “32” in figure 3) includes said first guide (see screw anchor “102” in figure 3) engageable with said first mounting member (see screw “92” in figure 3), said second retaining member (see support “34” in figure 3) including said second guide (see screw anchor “104” in figure 3) engageable with said second mounting member (see screw “94” in figure 3).
- Claim 22: An apparatus as defined in claim 21 wherein said first guide (see screw anchor “102” in figure 3) extends from said outer surface (see outer surface “52” in

figure 3) of said first retaining member (see support “32” in figure 3) and is engageable with the first vertebra, said second guide (see screw anchor “104” in figure 3) extending from said outer surface (see outer surface “54” in figure 3) of said second retaining member (see support “34” in figure 3) and being engageable with the second vertebra.

- Claim 35: An apparatus as defined in claim 1 wherein said core (see supple nuclear central portion “24” of resilient disc body “20” in figure 3) includes a radially outer surface (see left and right sides of “24” in figure 3) extending between said first (see upper surface of “24” in figure 3) and second (see lower surface of “24” in figure 3) surfaces of said core, said radially outer surface facing a portion (see right end of leg “42” of “32” in figure 3) of one of said first (see support “32” in figure 3) and second (see support “34” in figure 3) retaining members, said radially outer surface being spaced from said portion of said one of said first and second retaining members, said core deflecting into engagement with said portion of one of said first and second retaining members upon relative movement between said first and second retaining members.
- Claim 36: An apparatus as defined in claim 35 wherein said radially outer surface (see left and right sides of “24” in figure 3) of said core (see supple nuclear central portion “24” of resilient disc body “20” in figure 3) faces a portion (see right end of leg “42” of “32” in figure 3) of said first retaining member (see support “32” in figure 3), said radially outer surface of said core being spaced from said portion of said first retaining member, said core deflecting into engagement with said portion of said first retaining member upon relative movement between said first and second retaining members, said radially outer surface facing a portion (see right end of leg “44” of “34” in figure 3) of

said second retaining member (see support "34" in figure 3), said radially outer surface being spaced from said portion of said second retaining member, said core deflecting into engagement with said portion of said second retaining member upon relative movement between said first and second retaining members.

- Claim 39: An apparatus as defined in claim 1 wherein said inner surface (see inner surface "62" in figure 3) of said first retaining member (see support "32" in figure 3) is concave, said first surface (see upper surface of "24" in figure 3) of said resilient core (see supple nuclear central portion "24" of resilient disc body "20" in figure 3) being convex.
- Claim 40: An apparatus as defined in claim 39 wherein said inner surface (see inner surface "64" in figure 3) of said second retaining member (see support "34" in figure 3) is concave, said second surface (see lower surface of "24" in figure 3) of said resilient core (see supple nuclear central portion "24" of resilient disc body "20" in figure 3) being convex.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. (US 6,156,067) in view of Patil (US 4,309,777). Regarding both claims

37 and 38, Bryan et al. disclose the apparatus as defined in claim 1 (see above) but do not teach a flange located on the retaining members. Patil teaches an intervertebral disc wherein said first retaining member (see disc portion "12" in figure 2) includes a flange (see extension from bottom of "12" in figure 2) extending toward said second retaining member (see disc portion "14" in figure 2), said flange having a radially inner surface facing said core (see compression springs "16" in figure 2) and spaced from said core, said second retaining member including a flange (see extension from top of "14" in figure 2) extending toward said first retaining member, said flange of said second retaining member having a radially inner surface facing said core and spaced from said core. Taking the invention disclosed by Bryan et al. and modifying the retaining members (see specifically legs "42" and "44" of supports "32" and "34" in figure 3 of Bryan et al.) to include a flange extending toward the other retaining member, as suggested by Patil, would restrict the amount of compression of which the core (see supple nuclear central portion "24" of resilient disc body "20" in figure 3 of Bryan et al.) is capable. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make this modification since doing so allows the invention to more closely imitate the natural motion of the vertebrae.

Claims 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889) in view of Marnay (US 5,314,477). Regarding claims 41-44, Harrington discloses the apparatus as defined in claim 1 (see above) but does not teach that the retaining members are engageable with a surgical tool. Regarding claims 41 and 43, Marnay teaches an intervertebral disc prosthesis wherein the first retaining

member (see plate “110” in figure 1) includes a portion (see holes “115” and “116” in figure 1) engageable with a surgical tool, said portion includes an opening (see holes “115” and “116” in figure 1) into which a portion (see rods “812” and “813” in figures 10 and 11) of the surgical tool extends. Regarding claims 42 and 44, Marnay teaches an intervertebral disc prosthesis wherein the second retaining member (see plate “120” in figure 1) includes a portion (see holes “125” and “126” in figure 1) engageable with a surgical tool, said portion includes an opening (see holes “115” and “116” in figure 1) into which a portion (see rods “822” and “823” in figure 10) of the surgical tool extends. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the retaining members (see upper member “32” and lower member “34” in figure 2 of Harrington) of the invention disclosed by Harrington to include openings for a surgical tool, as suggested by Marnay, to facilitate insertion of the artificial disc into the intervertebral space.

Claims 1, 14, 15, 19, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuras (US 2004/0122517 A1) in view of Camino et al. (US 6,086,613) and Forriol Pico (EP 1 285 632 A1).

- Claims 1 and 19: Kuras discloses an apparatus for replacing a damaged spinal disc in a spinal column, said apparatus comprising: an artificial disc, said artificial disc including a resilient core (see resilient core “60” in figure 3) having a first surface (see upper surface “62” in figure 3) and a second surface (see lower surface “64” in figure 3), a first retaining member (see upper retaining member “20” in figure 3) connected to said first surface of said resilient core, and a second retaining member (see lower retaining

Art Unit: 3733

member "40" in figure 3) connected to said second surface of said resilient core, said first retaining member having an outer surface (see outer surface "22" in figure 3) engageable with a first vertebra of the spinal column and an inner surface (see inner surface "24" in figure 3) facing said first surface of said resilient core, said second retaining member having an outer surface (see outer surface "42" in figure 3) engageable with a second vertebra of the spinal column and an inner surface (see inner surface "44" in figure 3) facing said second surface of said resilient core. Kuras teaches that the retaining members have axially extending openings (see openings "30" and "50" in figure 3). Kuras fails to teach first and second mounting members connectable with the vertebrae and the artificial disc to position the artificial disc between the first and second vertebrae, the mounting members being engageable with the artificial disc after being connected to the vertebrae to guide movement of the artificial disc into position between the first and second vertebrae. Camino et al. teach a spacer assembly wherein the central portion (see spacer "12" in figure 2) is attached to the vertebrae through the use of upper and lower mounting members (see end caps "10" in figure 2). Forriol Pico teaches a bone plate wherein the mounting members (screws) are inserted prior to insertion of the plate (see column 2, lines 42-46). This is advantageous because it allows the surgeon to take the patient's anatomy into consideration since he is able to visualize the insertion site (see column 3, lines 44-47) and then allows the surgeon to use the mounting members as indicators of where the plate will be positioned. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Kuras artificial disc with mounting

members, as suggested by Camino et al., in the axially extending openings, as doing so would allow the surgeon to visualize the site where he would be placing the mounting members (this would ensure that the surgeon would not place the mounting members in an area where either vertebra is too damaged to sufficiently engage the mounting members) and then use the mounting members as indicators of where the disc would be positioned.

- Claims 14 and 30: In light of the modifications to Kuras in view of Camino et al. and Forriol Pico, the mounting members would include inner surfaces (see inner ends "52" in figure 2 of Camino et al.) facing the core and spaced from the core, and the core would be able to deflect into engagement with the inner surfaces of the mounting members upon relative movement between the first and second retaining members (see figure 5 of Kuras, which shows the deflection of the core into the openings of the retaining members).

- Claims 15 and 31: Kuras in view of Camino et al. and Forriol Pico disclose the claimed invention except that the inner surfaces of the mounting members are concave. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the inner surfaces of the mounting members such that they are concave, since applicant has not disclosed that such a shape solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an engagement surface for engagement with the core. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Response to Arguments

Applicant's arguments, see pages 16-17, filed 3 March 2008, with respect to the abstract have been fully considered and are persuasive. The objection to the abstract has been withdrawn.

Applicant's arguments, see pages 17-18, filed 3 March 2008, with respect to the statutory double patenting rejection of claims 1-3 and 5 have been fully considered and are persuasive. The statutory double patenting rejection has been withdrawn.

Applicant's arguments, see pages 24-29, filed 3 March 2008, with respect to the rejection of claims 1, 14, 15, 19, 30, and 31 under 35 U.S.C. §103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground of rejection is made in view of newly found prior art references (see the 35 U.S.C. §103(a) rejection using Kuras in view of Camino et al. and Forriol Pico above).

The remainder of applicant's arguments filed 03 March 2008 have been fully considered but they are not persuasive.

Rejection of Claims 1-3, 5-13, 16-21, 23-29, and 32-34 under 35 U.S.C. §102(b)

Applicant argues that Harrington (US 5,893,889; hereinafter "Harrington") does not anticipate claim 1 because the mounting members of Harrington engage the prosthetic disc before being connected to the first vertebra rather than after being connected to the vertebrae. Applicant also argues that the screws do not guide movement of the artificial disc into position between the vertebrae because the surgeon

has already positioned the disc before the screws are tightened. The examiner respectfully disagrees. The phrase, "said first mounting member being engageable with said artificial disc after being connected to the first vertebra to guide movement of said artificial disc into position between the first and second vertebrae," is a statement of intended use. With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Harrington, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Also, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). In the instant case, the Harrington device could accomplish the intended use if the surgeon were to insert the device using the following steps: (1) place the device, not including the screws, between the vertebrae; (2) loosely insert at least one but no more than two (i.e., screws 47 and 64) screws; (3) using the at least one screw as a guide, shift the device so it is in the intended position; (4) loosely insert the remaining screws while holding the device in the intended position; and (5) tighten the screws.

Rejection of Claims 1-4, 19-22, 35, 36, 39, and 40 under 35 U.S.C. §102(b)

Applicant argues that Bryan (US 6,156,067; hereinafter "Bryan") does not anticipate claim 1 because the mounting members of Bryan engage the disc before being connected to the first vertebra rather than after being connected to the vertebrae. Applicant also argues that the screw does not guide movement of the disc into position between the vertebrae because the surgeon has already positioned elements 32 and 34 before the screws are inserted. The examiner respectfully disagrees. The phrase, "said first mounting member being engageable with said artificial disc after being connected to the first vertebra to guide movement of said artificial disc into position between the first and second vertebrae," is a statement of intended use. With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Bryan, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Also, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). In the instant case, the Bryan device could accomplish the intended use if the surgeon were to insert the device using the following steps: (1) place the device, not including the screws, between the vertebrae; (2) loosely insert at least one screw; (3) using the at least one screw as a guide, shift the device so it is in the

Art Unit: 3733

intended position; (4) loosely insert the remaining screw, if not previously inserted, while holding the device in the intended position; and (5) tighten the screws.

Rejection of Claims 37 and 38 under 35 U.S.C. §103(a)

Applicant argues that claims 37 and 38 are allowable because they depend, directly or indirectly, from claim 1, which, according to applicant's previous argument, is not anticipated under 35 U.S.C. §102(b) by Bryan. The examiner respectfully disagrees. Claim 1 is anticipated under 35 U.S.C. §102(b) by Bryan for the reasons stated above.

Rejection of Claims 41-44 under 35 U.S.C. §103(a)

Applicant argues that claims 41-44 are allowable because they depend, directly or indirectly, from claim 1, which, according to applicant's previous argument, is not anticipated under 35 U.S.C. §102(b) by Harrington. The examiner respectfully disagrees. Claim 1 is anticipated under 35 U.S.C. §102(b) by Harrington for the reasons stated above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733